

## **REMARKS**

### **I. Preliminary Remarks**

There are no amendments filed with this response.

### **II. Patentability Arguments**

#### **A. The Rejections of Claims 26, 41-46 and 54 Under 35 U.S.C. § 103(a) Should be Withdrawn**

At page 3 of the final office action, the Examiner maintained his previous assertion that claims 26 and 41-54 are unpatentable over US Patent Application 2002/0085997 to Schmidt et al. ("Schmidt") in view of Sun et al. in Cancer Gene Ther. 2(3): 183-190, 1995 ("Sun") and U.S. patent 6,277,368 to Hiserodt et al., filed on October 29, 1996 and issued on August 21, 2001 ("Hiserodt") because according to the Examiner, the Schmidt/Sun/Hiserodt combination renders instant claims 26 and 41-54 obvious under 35 U.S.C. 103(a).

At page 4 of the office action, the Examiner rejected applicants' argument that Schmidt teaches away from the instant invention as defined by claims 26, 41-54. The Examiner relied on *In re Susi* for the proposition that "disclosed examples and preferred embodiments do not constitute teaching away from a broader disclosure or nonpreferred embodiments." *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). In that case, the court held that "appellant is essentially in the position of one who argues that the selection of a relatively small subgenus from a genus disclosed in the prior art would have been unobvious at the time of his invention to one skilled in the art." *Id.*, at 445. The art cited against *Susi* disclosed both: the invention that *Susi* was attempting to claim **and** preferred embodiments that did not include the *Susi* invention. On these facts, the *Susi* court held that disclosed examples and *preferred embodiments* do not constitute teaching away from a broader disclosure or *non-preferred embodiments* which did disclose the *Susi* invention.

Unlike *In re Susi*, Schmidt does not provide the broad disclosure that would include Applicant's invention. In paragraph [0023], Schmidt provides "*The invention* relates to a tumour vaccine . . . consisting of tumour cells . . . which present peptides derived from tumour cells. . . ." Thus, Schmidt limits its invention to tumor cells charged with a peptide and specifically states that the invention does not include as a non-preferred embodiment a vaccine in which cells are transfected with a DNA coding for the peptide. Specifically, in paragraph [0021] Schmidt states that "In contrast to approaches in which . . . the antigen is presented via transfection with a DNA coding for the protein, *the invention* is to provide a vaccine which triggers an efficient immune response whilst being simpler to manufacture." Even when the Schmidt reference discusses transfecting cells with DNA, it refers to publications that describe transfection with cloned sequences that code for specific polypeptides (see paragraph 21, which cites WO92/20356, WO94/05304, WO94/23091, and WO95/00159) while the present application teaches the transfection of antigen presenting cells (not tumor cells) with total genomic DNA from a tumor in an animal to be treated with the vaccine and which cells are semi-allogeneic.

At page 4 of the office action, the Examiner also relies on *Celeritas Technologies Ltd. V Rockwell International Corp.* The Examiner correctly states the holding of the case as that the prior art *anticipated* the claims despite the prior art's negative treatment of the invention claimed by the claims. However, in the present case, the Examiner did not allege anticipation, but rather, it is obviousness and thus the Applicant respectfully submits that *Celeritas* is not applicable, especially since, as discussed above, it does not teach or even suggest the present invention.

At page 5 of the office action, in the paragraph bridging pages 4 and 5, the Examiner writes "Applicant's arguments that Schmidt teaches away from a method of transfection of antigen-presenting cells with DNA is not persuasive since the method is disclosed and may constitute a non-

preferred embodiment.” Again as stated above when discussing transfection with DNA, Schmidt refers to publications that describe transfection of cells with cloned sequences that encode tumor-associated antigens and not transfection of antigen presenting cells with total genomic DNA isolated from the tumor of an animal to be treated with the vaccine as presently claimed.

Further, as stated above, Schmidt discourages the use of transfection with a DNA encoding a tumor associated antigen for the purpose of making an anti-cancer vaccine and states that cancer cells charged with a tumor associated antigen or polypeptide or portion thereof should be used for the purpose.

To summarize, Schmidt does not, *inter alia*, disclose or suggest the use of total genomic DNA from an animal’s tumor to transfect an antigen presenting cell that is not a tumor cell according to the present invention, but rather teaches away from transfection as a method for preparing a vaccine.

Applicant also respectfully submits that if a first prior art reference “teaches away from a second reference, then that finding alone can defeat [an] obviousness claim” based on a combination of the two references. *Winner International Royalty Corp. v. Wong*, 202 F.3d 1340, 53 USPQ2d 1580 (Fed. Cir. 2000).

Because Schmidt discourages the use of transfection to prepare a vaccine, and further utilizes tumor cells charged with polypeptides, the Applicants further submit that the requisite motivation to combine the reference with Sun et al. is absent and thus the rejection should be withdrawn.

Alternatively, even if there were motivation to combine, Sun does not remedy the deficiencies of Schmidt, in part because Sun does not teach or suggest an antigen-presenting cell expressing at least one class I MHC or class II MHC determinant that is syngeneic and at least one class I MHC or class II MHC determinant that is allogeneic to a vaccine recipient as is presently

claimed. Sun is limited to allogeneic cells. In summary, given the teaching of Schmidt against use of transfection with DNA encoding tumor antigens, there is no motivation to combine teachings of Schmidt and Sun, and further, Sun does not teach an antigen-presenting cell coexpressing syngeneic and allogeneic determinants which are transfected with total DNA from the tumor of an animal to be treated as presently claimed.

At page 7 of the office action, the Examiner characterizes Hiserodt as teaching development of a cellular composition and method for using it in cancer immunotherapy, particularly in human patients. Hiserodt does not teach or suggest that a vaccine comprise an antigen-presenting cell expressing at least one class I MHC or class II MHC determinant that is syngeneic and at least one class I MHC or class II MHC determinant that is allogeneic to a vaccine recipient and that transfected with tumor genomic DNA derived from a tumor in an animal to be treated with the vaccine. Thus, Hiserodt does not remedy deficiencies of Schmidt and Sun.

In summary, there is no motivation to combine teachings of Schmidt with those of Sun and Hiserodt. Further, the combination of references does not teach or suggest the subject matter of the present claims. Because of these failures, the cited combination of references cannot render the claims obvious as a matter of law, therefore, the rejection under 25 U.S.C. 103(a) can be properly withdrawn and the withdrawal is respectfully requested.

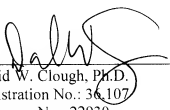
**Conclusion**

Applicant respectfully submits that claims, as currently amended, are in condition for allowance and early notification thereof is requested. If in the interest of expediting prosecution, the Examiner has questions or comments he is invited to telephone the undersigned at the indicated telephone number.

HOWREY, LLP

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